REMARKS

Claims 1, 2, 6, 8, 11 - 15, 20, 23, 25, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi. In response, claims 1, 15 and 23 have been amended to further distinguish Lethi. In particular, these independent claims have been amended to specify that the nasal catheter does not restrict the patient's spontaneous respiration through the nasopharynx, unlike Lethi, (or through the oropharynx, unlike the Brekke patent cited in the previous Office Actions).

Lethi's tube 1 includes an inflatable cuff 3 that creates an air-tight obstruction between the nasopharynx and the rest of the patient's breathing passage. The cuff 3 is intended to block unwanted secretions from the nasal area from draining into the throat and lungs (col. 5, lines 23 - 26). However, the cuff 3 also blocks nasal respiration, except through the tube 1. With unrestricted spontaneous breathing, the nasopharynx serves to heat, humidify and filter air. These natural functions are prevented with the Lethi invention. Lethi's device is similar to other conventional artificial airways (e.g., nasopharyngeal airways, nasotracheal and oral endotracheal tubes) in that resistance to air flow (and restriction of spontaneous breathing) can be high and the work of breathing through the passageway of the airway is significantly increased. The single most important factor affecting ventilatory muscle function and work of breathing is the artificial airway, even if the patient is on ventilatory assistance. The increase in resistance and restriction to breathing through an artificial airway can be most devastating with pre-existing ventilatory muscle dysfunction (i.e., patients with respiratory failure or insufficiency), but resistance and restriction may also precipitate fatigue in previously healthy individuals if the patient's ventilation requirements are high.

The central passage in Lethi's tube is also intended to allow introduction of feeding tubes, suction catheters and observation probes. Lethi calls for having the cuff inflated during these procedures to prevent inadvertent dislodgement of the airway when such devices are removed. Placement of these devices in the breathing passage further increases resistance and restriction to breathing through the tube, and the inflated cuff prohibits any nasal breathing around the airway.

The Lethi device is intended for short-term use in surgery or post-op recovery or "waking up" period and is also advocated for use in emergency and critical care. Nasopharyngeal airways such as the Lethi device are indicated for maintaining a breathing passage in patients who can not maintain an airway due to an altered level of consciousness due to anesthesia or acute illness. These individuals can tolerate a large airway in the nasopharynx and back of their throat. However, truly conscious patients will not likely tolerate the large airway and inflated cuff pushing against the soft palate and throat, because they will produce a gag reflex, aerophagia, or air swallowing and interfere with, or restrict eating and drinking. In contrast, the present small nasopharyngeal catheter can be inserted nightly before bed by patients with sleep apnea and chronic respiratory failure and insufficiency. Patients with acute respiratory failure or insufficiency can use it continuously for days and the functions of eating and drinking will not be restricted.

In addition, nothing in Lethi teaches or suggests a gas source with a flow rate of 4 - 40 liters per minute. The primary lumen of the tube 1 is apparently intended only as a conduit for the patient's spontaneous respiration. Lethi discloses a second, oxygen supply lumen 5 or 5b built into the wall of the tube 1. The typical flow rate of 1 to 2 L/min is generally adequate to correct blood oxygen levels. However, nothing in Lethi teaches or suggests the claimed range of flow rates. Delivering excessive pure oxygen at such flow rates tends to suppress the patient's respiration through ablation of the hypoxic respiratory drive, and may result in a type of respiratory failure called CO_2 narcosis, which is a potentially fatal condition for the patient. Similarly, excessive oxygen administration may cause a condition called oxygen toxicity.

The oxygen supply lumen 5 in Lethi's device is suitable only for delivering low flow rates of oxygen, which can be beneficial in correcting low blood oxygen levels. In contrast, the present invention delivers a high flow rate of air (or air enriched with oxygen) that goes beyond the goal of improving blood oxygen levels to reduced the patient's work of breathing, improve alveolar ventilation, or wash out of carbon dioxide from the patient's airway, as specified in amended claims 1, 15 and 23.

As to claims 14 and 28, nothing in Lethi teaches or suggest the use of helium. The low density and viscosity of helium significantly reduce the patient's work of breathing.

Claims 3 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Bowden et al. Claim 24 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Linder et al. In response, Applicant notes that trimming the length of the Lethi device would destroy its functionality. The integrity of the inflatable cuff 3 would be lost if the distal end of the Lethi device is trimmed. The connectors, cuff inflation lumen, and safety flange 2 would be lost if the proximal end of the Lethi device is trimmed. In addition, Applicant notes that all of these are dependent claims. Applicant submits that the invention defined in each of these dependent claims should be considered as a whole. The specific elements provided by each of these dependent claims should be considered in combination with the elements of their respective independent claims, rather than as isolated elements by themselves.

Claims 5 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Dali et al. These claims require a delivery tube with two opposing end connectors and a cap that is removably insertable into the unattached end connector. Dali et al. have been cited as showing a removable cap. In response, Applicant submits that Lethi's extension tube 9 is not a delivery tube as required in these claims because it does not have two opposing ends with connectors for attachment to the gas source.

Claims 4 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Brain. Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Daniell et al. In response, Applicant notes that these are dependent claims and restates the previous comments concerning amended independent claims 1, 15 and 23.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

DORR, CARSON, SLOAN & BIRNEY, P.C.

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By: Thomas S Birney

Thomas S. Birney #30,025
3010 East 6th Avenue
Denver, Colorado 80206
(303) 333-3010

Attorneys for Applicant